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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,815	12/20/2004	Andrew Bailey	100729-1P US	8233
22466 7590 05/01/2007 ASTRA ZENCA PHARMACEUTICALS LP GLOBAL INTELLECTUAL PROPERTY 1800 CONCORD PIKE WILMINGTON, DE 19850-5437			EXAMINER BERCH, MARK L	
			ART UNIT 1624	PAPER NUMBER
			MAIL DATE 05/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,815	Applicant(s) BAILEY ET AL.	
	Examiner Mark L. Berch	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 10-13 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/20/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-6 and 10-13 are rejected as being drawn to an improper Markush Group. The claims are drawn to multiple inventions for reasons set forth in the above requirement for restriction. This does not constitute an art recognized genus. Because of the marked structural differences at a part of the molecule essential for utility, the claims are deemed to lack unity of invention (see *In re Harnish*, 206 USPQ 300). The claims are examined only to the extent that they read on the elected invention. Cancellation of the non-elected subject matter, i.e. limitation to purines will overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, are rejected under 35 U.S.C. 102(a,e) as being anticipated by 6921753.

The 102a date is based on the date in field (65).

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See species at the top of column 69, corresponding to Y=NH, p=1, R7=naphthyl, R=H. In addition, the species at lines 41-42 is the same but with R as cycloalkyl with an O present, assuming that this is what the claim language really means (see next rejection).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the definition of R, alkyl or cycloalkyl "which can optionally contain one or more O..." does not make sense. An alkyl cannot contain O.. Does applicant intend alkyl substituted by O, etc.? Is this O to be in the ring for cycloalkyl? The same problem occurs in the second branch of the R1 definition for R9/R10 at alkyl. For whichever choice is selected, applicants must show that one skilled in the art could have figured out that this choice, and not another, was surely intended.

Claims 1-3, 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The second branch of the R1 definition provides a definition in terms of itself. The NR9R10 ring can be substituted by NR9R10, which starts the definition all over again, providing for an infinite regress.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Cathepsin S, does not reasonably provide enablement for cysteine protease generally. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There is an immense range of diverse Cysteine Proteases.

There are Viral Cysteine Proteases which arise from viruses e.g. picornaviruses, (such as rhinoviruses, poliomyelitis, and hepatitis A viruses). There are Bacterial Cysteine Proteases e.g. from Staphylococcus or Streptococcus, and some from fungi as well. Dozens of Cysteine Proteases have been isolated from parasitic protozoa and worms. Cysteine Proteases from plants include not only the entire papain family but also the legumains and others. In mammals there is the large collection of Lysosomal Cysteine Proteases, including the assorted Cathepsins, but also other Lysosomal Cysteine Proteases, e.g. cysteine proteases such as TP-1 and TP-2. Mammals also have Cytoplasmic Cysteine Proteases, including the Calpains and others. The Merops classification system lists over 70 families of these. For example the ubiquitinyl hydrolase-L1 family has:

ubiquitinyl hydrolase-L1

ubiquitinyl hydrolase-YUH1

ubiquitinyl hydrolase-L3

ubiquitinyl hydrolase-BAP1 -

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ubiquitinyl hydrolase-UCH37

ubiquitinyl hydrolase isozyme L4

ubiquitinyl hydrolase UCH-D

The calpain family has:

calpain-1

calpain-2

calpain C

calpain-3

calpain-9

calpain-8

calpain-7

calpain tra-3

calpain-15

calpain-5 -

calpain-11

calpain A

calpain B

calpain-12

calpain-10

phyto-calpain

calpain-13

calpain-14

Tpr peptidase

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calpain

calpain B -

calpain M

calpamodulin

The hedgehog family has:

hedgehog protein

Sonic hedgehog protein

Indian hedgehog protein

Desert hedgehog protein

Tiggy-winkle protein

Warthog protein 4

Warthog protein 8

The bacteriocin-processing peptidase family has 7 members; plum pox virus family has 13 members; the caspase family has more than 40; the papain superfamily has more than 130 identified so far. There is no such thing as a compound which is effective against Cysteine Proteases generally; the enzymes are simply too diverse.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663.

The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Mark L. Berch
Primary Examiner
Art Unit 1624

4/26/2007